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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/831,901 | 08/07/2001 | Kanji Takada | P21010 | 2415 |

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| EXAMINER |
|---|
| JOYNES, ROBERT M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 10/01/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/831,901 | TAKADA, KANJI | |
| | Examiner | Art Unit | |
| | Robert M. Joynes | 1615 | |

*-- Th MAILING DATE of this communication appears on the cov r sh et with the correspondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Receipt is acknowledged of applicants' Preliminary Amendment filed on August 7, 2001 and Information Disclosure Statement filed on October 2, 2001.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US 4765983) in combination with Caldwell et al. (US 4767627). Takayanagi teaches an adhesive medical tape containing an active agent in an adhesive layer and a support layer (Col. 1, line 55 – Col. 2, line 12). The drug is contained in a water-soluble polymer layer (Col. 2, line 58 – Col. 3, line 5). The medicament layer can be composed of one or more layers (Col. 3, lines 18-41). The support layer is composed of an intestine soluble polymer such as hydroxypropyl methylcellulose phthalate or poly(methacrylic acid, methylmethacrylate) (Col. 3, line 50

– Col. 4, line 4). The support layer thickness is from 2 to 20 microns and the medicament layer thickness is from 20 to 300 microns (Col. 10, Claim 4).

Takayanagi does not expressly teach that the film is contained within a capsule.

Caldwell teaches a planar disc comprising at least one erodible polymer and an active agent (Col. 42-62). This planar disk can be made from erodible polymers or non-erodible polymers (Col. 5, line 46 – Col. 6, line 23). The erodible polymers can be hydroxypropyl methylcellulose phthalate or poly(methacrylic acid) (Col. 5, lines 46-68). The drug can be present in an erodible matrix or non-erodible matrix (Col. 6, lines 24-44). One matrix can be attached to the other for administration of the matrix (Col. 6, lines 24-44). The matrix is then compressed by folding or rolling and then inserted into a capsule for delivery (Col. 4, lines 22-32). The active agent in not critical and can be any active in it stable form (Col. 6, lines 55-68).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a film or tape comprising an active agent in a matrix of polymers and to place that tape or film in a capsule for oral administration.

One of ordinary skill in the art would have been motivated to do this to retain a dosage form in the stomach fro an extended period of time thereby improving bioavailability of the drug (Caldwell, Col. 3, lines 3-11).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US 4765983) in combination with Caldwell et al. (US 4767627) in

further combination with Uyama et al. (US 6086869). The teachings of Takayanagi and Caldwell are discussed above. Neither Takayanagi not Caldwell teach the active agent to be interferon.

Uyama teaches that interferon can be orally administered in various forms. (Col. 6, Claim 7).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to place an active agent such as interferon in a film composition that is administered in capsule form.

One of ordinary skill in the art would have been motivated to do this to treat various diseases such as retinal edema.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 28, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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